Mountain-Pacific Quality Health . . . The go-to resource for driving innovation in health care systems

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Montana Medicaid Prior Authorization Request Form for Use of Olysio®(simeprevir)

Olysio® Initial Approval Form

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Today's Date:	Anticipated Olysio Start Date:

I. Patient Readiness Evaluation:

Patient psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The patient must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Given the high cost of Hepatitis C treatment, we want to ensure that both the provider and the patient feel that the patient is committed to effectively start and successfully adhere to treatment. We highly recommend that you use a patient readiness evaluation tool such as Prep-C, a free interactive online tool which can be found at the following website: https://prepc.org/. **Please discuss the following questions with your patient, document their responses below, and have patient sign page 2:**

1. **Does patient have a history of alcohol abuse? Yes No**
   - If yes, how long has it been since patient last used alcohol?
   - If yes, is patient attending a support group or receiving counseling? Yes No
2. **Does patient have a history of injectable drug abuse? Yes No**
   - If yes, how long has it been since patient last used an injectable drug?
   - If yes, is patient attending a support group or receiving counseling? Yes No
3. **Does patient have a history of any other controlled-substance abuse? Yes No**
   - If yes, how long has it been since patient last used this substance?
   - If yes, is patient attending a support group or receiving counseling? Yes No
4. **Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No**
   - If yes, how will compliance/ involvement be improved?
5. **Does patient have mental health conditions that are not being adequately treated? Yes No**
   - If yes, please explain, and state the plan for treatment:
6. **Does patient have adequate social support? Yes No**
   - If not, please state a plan to improve support:

MT Medicaid Hepatitis C Patient Readiness Criteria:

1. Patient must not have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least 6 months prior to starting Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.

2. Patient must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.

3. Patient must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.

4. If patient has mental health conditions, patient must be compliant with mental health medications and/or psychotherapy. If patient has mental health conditions that are not currently being treated, then a mental health consult to assess for patient readiness will be required before Hepatitis C treatment can begin.

Patient signature:_____ **Date:**_____

II. MT Medicaid Olysio® Requirements:

Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive tests: APRI score, FibroSure score, or FibroScan results]

_____

List any previously tried Hepatitis C treatments and response:

_____

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Patient must meet ALL of the following criteria: (Please check all that apply)

- ○ Patient Readiness Evaluation (page 1) must be completed and patient must meet all of the Patient Readiness Criteria listed on page 2
- ○ Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive test results: APRI score, FibroSure score, or FibroScan results]
- ○ All chart notes related to Hepatitis C evaluation/treatment must be included
- ○ Diagnosis of chronic Hepatitis C, **genotype 1**.
- ○ Does patient have genotype 1a? Yes/ No **(please circle**). **If yes, must provide lab result of screening of NS3 Q80K polymorphism.** If polymorphism is present, alternative therapy should be considered due to decreased efficacy.
- ○ Must not be of East Asian ancestry.
- ○ Never had previous treatment with Olysio® or other HCV NS3/4A protease inhibitors [ex: Victrelis® (boceprevir) or Incivek® (telaprevir)]
- ○ Patient is 18 years of age or older.
- ○ Must receive concomitant peg-interferon and ribavirin
- ○ Must be prescribed by (or had a documented consult with) a gastroenterologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis. Notes of consultation with specialist must be attached.
- ○ Patient must not have a history of liver transplant
- ○ Must not have moderate or severe hepatic impairment (Child-Pugh Class B or C)
- ○ Female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment.
- ○ Patient must not be taking any of the following medications that are not recommended to be coadministered with Olysio®. **Please circle medication name if patient is taking any of the following:** erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, rifampin, rifabutin, rifapentine, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, dexamethasone, cisapride, cobicistat-containing product, efavirenz, delavirdine, etravirine, nevirapine, darunavir/ritonavir, atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, milk thistle, or St. John's wort.

Limitations:

1. Total duration of therapy to be authorized is **12 weeks**.
2. **Initial approval** will be granted for **8 weeks**. This allows for 4 week HCV RNA viral load lab results to be received. Dosing will be limited to **1 capsule per day (28 capsules/28 days)**.
3. Continuation of therapy will require documentation of HCV RNA viral load at 4 weeks in therapy.

Provider's Signature: _____ **Date:** _____

Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350

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Montana Medicaid Prior Authorization Request Form for Use of Olysio® (simeprevir)

Olysio® Renewal Form

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Date:	

Requirements:

All of the following requirements must be met: **(Please check all that apply)**

- ○ Peg-interferon alfa and/or ribavirin must not have been discontinued
- ○ Patient must have been compliant with peg-interferon alfa, ribavirin, and Olysio® therapy as per protocol
- ○ Week 4 HCV RNA level must be documented below:

Date Olysio® was started: _____

Week 4 HCV RNA viral load (IU/ml): _____ Lab Date: _____

Limitations:

1. If **week 4** HCV RNA is ≥ **25 IU/ml**, further authorization will be **denied**.
2. If **week 4** HCV RNA is < **25 IU/ml**, Olysio® therapy will be **authorized for 4 weeks** (for a maximum total of 12 weeks of Olysio® therapy). Dosing will be limited to 1 capsule per day (28 capsules per 28 days).

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